Missouri Board of Pharmacy

2023 Missouri Pharmacy Practice Guide

Supplement

August 17 | 2023

MESSAGE FROM THE BOARD

The Missouri General Assembly substantially amended multiple provisions of Chapter 338, RSMo, during the 2023 legislative session. This supplement summarizes the 2023 legislative changes which are effective as of August 28, 2023, and provides additional information on recent rule updates since the original 2023 Missouri Pharmacy Practice Guide was published in February 2023.

The 2023 Missouri Pharmacy Practice Guide Supplement is provided for informational purposes only. This Supplement does not constitute a rule statement of general applicability or binding law. Additionally, the 2023 Supplement does not constitute a comprehensive review of all recent statutory/rule changes. Other provisions of Missouri law may have changed which are not reflected in this document.

To ensure compliance, licensees should thoroughly review Chapter 338, RSMo, 20 CSR 2220 and all other applicable state and federal laws. Statutes/rules may have changed since this document was issued. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The term "should" represents Board/staff recommendations. The Board of Pharmacy expressly reserves the right to revise the contents as deemed appropriate or necessary. Questions regarding this document may be addressed to the Board office.

Only those Practice Guide sections which have been amended by the Board are included in this Supplement; Licensees should review the full Missouri Pharmacy Practice Guide for additional compliance information/guidance.

Additional compliance resources and materials are available on the Board's website at http://pr.mo.gov/pharmacists. License and regulatory updates are also provided via e-alerts and the Board's electronic newsletter. To sign up for the Board's newsletter and e-alerts, visit www.nabp.net/indexmobop.asp or e-mail MissouriBOPNewsletter@nabp.net.

C.4 PRESCRIPTIVE AUTHORITY

Section 338.010.1 grants pharmacists authority to prescribe a prescription or over-the-counter "nicotine replacement therapy product." [See C.10 for additional information]. Effective August 28, 2023, pharmacists may also independently order and administer FDA approved vaccines as designated in § 338.010.1(4) (see supplement Section M for excluded vaccines/additional requirements).

Missouri law does not currently recognize other prescriptive authority for a pharmacist. However, pharmacists are authorized to perform the following additional activities:

- Initiate or modify medication therapy or devices with a certificate of medication therapeutic plan authority and medication therapy services protocol. This includes selecting a new or different medication or discontinuing medication (See Section N for requirements)
- Dispense an emergency supply of non-controlled medication if the pharmacist is unable to obtain refill authorization from the prescriber (See H.17);
- Dispense human immunodeficiency virus post-exposure prophylaxis (HIV PEP) pursuant to a protocol with a Missouri licensed physician (see C.12),
- Effective August 28, 2023, provide influenza, group A streptococcus and COVID-19 medication therapy services, with a certificate of medication therapeutic plan authority, as authorized by a Missouri DHSS statewide standing order (see Section N), and
- Dispense naloxone hydrochloride, naltrexone hydrochloride, or an opioid antagonist as defined by § 195.206 without a prescription pursuant to a statewide standing order or by protocol with a Missouri licensed physician (See C.11)

C.11 OPIOID OVERDOSE ANTAGONISTS/PREVENTION

Missouri pharmacists may dispense/distribute naloxone HCL, naltrexone HCL or an "opioid antagonist" either:

1. Under protocol with a Missouri licensed physician, or
2. Pursuant to a statewide standing order issued/approved by the Missouri Department of Health and Senior Services ("DHSS"), or
3. To a qualified first responder agency as defined by § 190.255, or
4. To any person/organization acting under a standing order issued by a healthcare professional who is authorized to prescribe an opioid antagonist

See § 190.255, § 195.206, and § 338.205.

Effective August 28, 2023, the definition of an "opioid antagonist" was expanded to include naloxone hydrochloride "*or any other drug or device approved by the [FDA] that blocks the effect of an opioid overdose and is administered in a manner approved by the [FDA] or any accepted medical practice method of administering*". [See § 195.206]

As of the date of this publication, Missouri DHSS has issued an active standing order for designated opioid antagonists that is available on the Board's website. Licensees must comply with all DHSS requirements, even if not otherwise required by Board statute/rule.

No additional Board or DHSS licensure, certification or training is required to dispense naloxone HCL, naltrexone HCL or an opioid antagonist. However, pharmacists must be competent to perform the services provided in accordance with applicable standards of care. An adequate medical record should be maintained for each patient that documents the care provided. At a minimum, the Board recommends maintaining the following records:

1. The patient's name, birthdate, address and telephone number
2. The date(s) the patient was seen
3. The patient's primary care provider (if provided)
4. Documentation of any patient screening/testing
5. Any pertinent medical or medication information/history
6. The name and dosage of any medication prescribed
7. Any recommended medication treatment plan(s) or follow-up consultation(s); and
8. Any healthcare provider referrals.

This list includes the Board's minimum recommendations. Pharmacists should use their professional judgment to determine if additional medical information is needed or required.

A variety of naloxone educational materials are available on the Board's website, including:

- The Opioid Overdose Prevention Toolkit published by the United States Substance Abuse and Mental Health Services Administration (SAHMSA), and
- An Opioid Safety and Naloxone Brochure for Missouri patients and caregivers. *(Complimentary copies can be requested by e-mailing MissouriBOP@pr.mo.gov or by contacting the Board office. Quantities may be limited).*

C. 12 HIV Post-Exposure Prophylaxis

Section 338.730 allows an "authorized pharmacist" to prescribe and dispense HIV post-exposure prophylaxis (PEP) pursuant to a written protocol with a Missouri licensed physician. 20 CSR 2220-6.025(1) defines an "authorized pharmacist" as a Missouri-licensed pharmacist with a current and active Missouri license who has completed a training course or certificate program in HIV antiretroviral prophylaxis that included training in CDC Guidelines for HIV PEP. No additional Board licensure, certification, or notification is required for authorized pharmacists who meet the requirements 20 CSR 2220-6.025. A Notification of Intent does not have to be filed.

Qualifying Protocols: For purposes of § 338.730, a qualifying HIV PEP protocol includes:

1. A written protocol approved by a Missouri-licensed physician that meets the minimum standards of 20 CSR 2220-2.625 and has been agreed to by the authorized pharmacist; or
2. A written protocol approved by the medical staff committee of a hospital or hospital system that includes a Missouri-licensed physician. "Medical staff committee" is defined as: *"The committee or other body of a hospital or hospital system responsible for formulating policies regarding pharmacy services and medication management"* (see § 338.165); or
3. A written protocol approved by the medical staff committee of a Missouri-licensed long-term care facility that includes a Missouri-licensed physician; or
4. A standing order issued by the Director of the Missouri Department of Health and Senior Services (DHSS) if a physician, or by a physician approved and designated by DHSS.

DHSS has not issued an HIV PEP standing order as of the date of this supplement. Licensees should monitor DHSS' website and the Board's e-alerts for additional updates.

SECTION C: PHARMACIST SCOPE OF PRACTICE

Protocol Requirements: Except as noted below for DHSS standing orders, HIV PEP protocols must adhere to CDC guidelines and include specific directions for the authorized pharmacist to follow. Except as otherwise provided for a DHSS protocol, HIV PEP protocols must be in writing and include the following minimum elements:

1. Directions/guidelines for patient assessment and counseling;
2. Authorized drug therapies to be dispensed including the specified dosage regimen and dosage forms;
3. Authorized route(s) of administration;
4. Specific requirements for referring patients to a healthcare provider for additional evaluation/treatment;
5. Any patient counseling requirements designated by the authorizing physician *(Note: Patient counseling is mandatory for HIV PEP under 20 CSR 2220-6.025(4)(B)*;
6. Any documentation or recordkeeping required by the authorizing physician.

HIV PEP protocols must be signed and dated by the authorizing physician and the authorized pharmacist. For protocols that include multiple physicians or authorized pharmacists, all participating physicians and authorized pharmacists may sign a statement agreeing to be governed by the protocol, in lieu of individual signatures. [20 CSR 2220-6.025(2)(D)].

Protocols must be physically or electronically maintained by both the authorized pharmacist and the authorizing physician for a minimum of eight (8) years after termination of the protocol. [20 CSR 2220-6.025(2)(F)].

DHSS standing orders must comply with DHSS requirements, and are exempt from the above signature requirements, unless otherwise required by DHSS.

> *Section 338.730 authorizes dispensing of HIV PEP only. However, pharmacists with a valid certificate of medication therapeutic services (MTS) may initiate/dispense both HIV PrEP and HIV PEP medication, if authorized by their MTS protocol.*

Standard of Care: Patient care activities must be safely and properly performed in accordance with the governing protocol, recognized standards of practice, and current CDC guidelines. Additionally, HIV PEP protocols must be within the skill, education, and competence of both the authorized pharmacist and the authorizing physician. [20 CSR 2220-6.025(3)]

Patient counseling is mandatory for all patients dispensed HIV PEP pursuant to a HIV PEP protocol. [20 CSR 2220-6.025(4)(B)]

Eligible Patients: An authorized pharmacist may dispense HIV PEP therapy under an HIV PEP protocol if:

1. The patient is thirteen (13) years old or older; and
2. The patient is HIV negative, as documented by a negative HIV test result obtained within the previous twenty-four (24) hours from an HIV antigen/antibody test, an antibody-only test, or a rapid, point-of-care fingerstick blood test approved by the FDA. The authorized pharmacist must order an HIV test if the patient does not have evidence of the required negative HIV test within the last twenty-four (24) hours.** If an HIV test is not reasonably available for twenty-four (24) hours or longer, the authorized pharmacist may use clinical discretion to dispense HIV PEP after verification that other dispensing criteria have been met and HIV PEP is otherwise indicated; and
3. The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms; and

4. The patient is not taking any contraindicated medications per guidelines and package insert information; and
5. The single high-risk event of non-occupational exposure to HIV occurred within seventy-two (72) hours of the pharmacist patient encounter. [20 CSR 2220-6.025(4)]

*** If the patient tests positive for HIV infection, the authorized pharmacist must immediately notify the patient and refer the patient to his/her primary care provider if known, and provide a list of providers and clinics in the patient's region for confirmatory testing and follow-up care. [20 CSR 2220-6.025(4)]*

An authorized pharmacist may not prescribe or dispense HIV PEP under 20 CSR 2220-6.025 if the patient is under thirteen (13) years old or is taking any contraindicated medications per guidelines and package insert information, and must immediately refer the patient to an emergency department or a primary care provider for urgent treatment.

A valid patient medical record must be maintained for each patient that documents the care provided that includes, at a minimum:

1. The patient's name, birthdate, address, and telephone number;
2. The date(s) the patient was seen;
3. The name or identity of the authorized pharmacist;
4. The patient's primary care provider, if provided;
5. Documentation of patient screening;
6. All information required by the governing protocol or requested by the authorizing physician;
7. Any other pertinent medical or medication information/ history;
8. The name and dosage of medication dispensed or prescribed under the authorizing physician's name; and
9. Any healthcare provider referrals.

Dispensing Limits: Unless otherwise provided by CDC guidelines or restricted by the governing protocol an authorized pharmacist may dispense a twenty-eight (28) day course of HIV PEP therapy to an eligible patient. However, an authorized pharmacist may not dispense HIV PEP to the same patient more than twice every three hundred sixty-five (365) days. Authorized pharmacists must notify patients of the three hundred sixty-five (365) day limit and advise patients that they must be seen by a primary care provider to receive subsequent prescriptions for HIV PEP if the patient exceeds the 365-day day dispensing limit. [20 CSR 2220-6.025(4)]

HIV PEP protocols may include a provision that allows an authorized pharmacist to create a prescription in the physician's name. The prescription must comply with all applicable state and federal law and may be dispensed by a licensed pharmacy.

20 CSR 2220-6.025 allows the prescription to be written under the authorized pharmacist's name or created in the authorizing protocol physician's name, if allowed by the governing protocol.

Patient Testing: In addition to prescribing and dispensing, an HIV PEP protocol may allow the authorized pharmacist to order or perform testing as designated by the protocol physician, medical staff committee, or DHSS.

If the protocol allows the authorized pharmacist to conduct physical assessments or to order and evaluate laboratory or other tests, the protocol must identify the required assessments, authorized tests that can be ordered, criteria for ordering the assessments and tests, interpretation of assessments/tests, and what action the authorized pharmacist is authorized to take based on assessment/test results. [20 CSR 2220-6.025(2)(C)]

Prescriber Notification: The authorized pharmacist must notify the patient's primary care provider when the pharmacist prescribes/ dispenses HIV PEP to the patient. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the authorized pharmacist must provide the patient a list of physicians and surgeons, clinics, or other healthcare service providers who the authorizing physician or the designee of the authorizing physician confirmed are willing and able to accept new or uninsured patients and deliver care in a timely fashion. The required list must be developed in consultation with or approved by the authorizing physician, and must be updated by December 31 of each calendar year and as needed to ensure patients have access to follow-up care and success with obtaining appointments.

If the patient does not have a primary care provider, the authorized pharmacist must also recommend that the patient use a patient healthcare navigator or community healthcare case worker as defined by the CDC to access healthcare services (see https://www.cdc.gov/dhdsp/chw_elearning/index.html). An authorized pharmacist must document authorization from the patient prior to facilitating referrals, coordinating follow-up care, or making appointments with a provider on the patient's behalf. [20 CSR 2220-6.025(4)(D)]

Mandatory Referrals: Authorized pharmacists must make the following referrals when prescribing/dispensing HIV PEP by protocol:

1. Patients who test positive for HIV, a sexually transmitted disease, or hepatitis B or C, must be referred or directed by the authorizing physician to a primary care provider and provided a list of providers or clinics in the patient's region for confirmatory testing and follow-up care.
2. Patients who return to the authorized pharmacist for follow-up care and show signs or symptoms of acute renal injury, acute HIV infection, acute drug toxicities, or serious side effects after taking HIV PEP, must be immediately referred by the authorized pharmacist to an emergency department for urgent evaluation and treatment.
3. Authorized pharmacists must report actual or suspected child abuse or neglect to the Missouri Department of Social Services (DSS), Children's Division, as required by Missouri law, including but not limited to sections 210.115 and 210.130, RSMo (see DSS Online System for Child Abuse & Neglect Reporting). If the case involves a known sexual assault victim, the authorized pharmacist must refer the patient to an emergency department, and recommend that the patient contact law enforcement and be examined and co-managed by professionals trained in assessing and counseling individuals who have been sexually assaulted. [20 CSR 2220-6.025(5)]

> *The governing HIV PEP protocol may include stricter limits/ requirements, in which event the governing protocol will control.*

- Additional Resources:
  - CDC HIV Information
  - CDC HIV PEP Guidelines

G.1 AUTHORIZED MISSOURI MID-LEVEL PRACTITIONERS

Chapter 334, RSMo, authorizes the following mid-level practitioners to prescribe both controlled and non-controlled substances under a collaborative practice agreement with a Missouri licensed physician:

- Advanced Practice Registered Nurses (APRN) [§ 334.104]
- Assistant Physicians (AP) [§ 334.037] ; and
- Physician Assistants (PA) [§ 334.747].

Assistant Physicians (AP) are different from Physician Assistants (PA). Assistant Physicians are recent medical school graduates who have not yet entered a residency program. Physician Assistants have medical training but do not have to be medicalschool graduates.

To prescribe controlled substances, an authorized Missouri mid-level practitioner must have a current BNDD and DEA registration. Mid-level practitioners cannot independently purchase, stock, dispense or administer controlled substances without a collaborative practice agreement with a Missouri licensed physician. *See G.4 for Non-Resident Mid-Level Practitioners.*

G.2 PRESCRIPTION REQUIREMENTS

To be valid for dispensing, prescriptions from a Missouri mid-level practitioner must include:

1. The date of prescribing;
2. The name of the patient(s), or if an animal, the species and owner's name;
3. For APRNs and APs, the name, telephone number and address of the mid-level practitioner and the supervising/collaborating physician. For verbal prescriptions, the name of the mid-level practitioner must be documented. *Effective August 28, 2023, the name of the collaborating physician is not required on Physician Assistant prescriptions [§ 334.735.4)(3)];*
4. For written prescriptions, the mid-level practitioner's manual signature or valid electronic signature as authorized by 20 CSR 2220-2.085 (*the supervising physician's signature is not required)*;
5. Name, strength and dosage of drug, device or poison prescribed and the directions for use;
6. The number of refills, if applicable;
7. The quantity prescribed in weight, volume, or number of units;
8. For controlled substances, prescriptions must comply with all state and federal controlled substance laws and include the patient's address, the mid-level practitioner's address, and the mid-level practitioner's DEA number. The collaborating physician's DEA number is not required.
9. Any other change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail, including, but not limited to, a change in quantity, directions, number of refills, or substitution authority. [See 20 CSR 2220-2.018, § 334.735.4 (Physician Assistants), 20 CSR 2150-2.240 (Assistant Physicians) and 20 CSR 2200-4.200(3)(G).7 (APRNs)].

Except as otherwise provided by law, prescriptions from mid-level practitioners must be based on a valid patient-practitioner relationship and must comply with all prescription requirements applicable to physicians. [See Section F]

G.3 REFILLS/QUANTITY LIMITS

The following refills/quantity limits are authorized for a Missouri mid-level practitioner (controlled substance guidance provided by BNDD):

Physicians may limit authorized refills/quantity limits in the governing collaborative practice agreement. If limited, the collaborative practice agreement will control.

	Missouri Advanced Practice Registered Nurse	Missouri Assistant Physicians	Missouri Physician Assistants
Non-Controlled Prescriptions	• Valid for 1 year • Refills/quantity limits as prescribed	• Valid for 1 year • Refills/quantity limits as prescribed	• Valid for 1 year • Refills/quantity limits as prescribed
Schedule II- Hospice Patients ***Effective August 28, 2023*	• 30-day quantity limit/ 90-days with documented medical reason • Prescription valid for 6-months from date issued. • APRN must be employed by a hospice provider certified by Missouri DHSS under Chapter 197 [See revised § 334.104.2(2) and § 195.070.2, effective August 28, 2022]	_____	• 30-day quantity limit/ 90-days with documented medical reason • Prescription valid for 6-months from date issued. • PA must be employed by a hospice provider certified by Missouri DHSS under Chapter 197 [See revised § 334.747.1(2) & § 334.735.8(2) effective August 28, 2022]
Schedule II	• Hydrocodone products only (includes single ingredient products) • Limited to a 5-day or 120-hour supply	• Hydrocodone products only (includes single ingredient products) • Limited to a 5-day or 120-hour supply	• Hydrocodone products only (includes single ingredient products) • Limited to a 5-day or 120-hour supply
Schedule III (Opiates)	• Limited to a 5-day or 120-hour supply • Prescription valid for 6-months from date issued. • No refills allowed***	• Limited to a 5-day or 120-hour supply • Prescription valid for 6-months from date issued • No refills allowed***	• Limited to a 5-day or 120-hour supply • Prescription valid for 6-months from date issued • No refills allowed***
Schedule III (Non-Opiates)	• Full authority to prescribe • 90-Day quantity limit • Prescription valid for 6-months from date issued.	• Limited to a 5-day or 120-hour supply • Prescription valid for 6-months from date issued. • No refills allowed	• Limited to a 5-day or 120-hour supply • Prescription valid for 6-months from date issued. • No refills allowed
Schedule IV & V	• Full authority to prescribe • 90-day supply limit for a single prescription • C-IV: Prescription valid for 6-months from date issued • C-V: Prescription valid for 12-months from date issued.	• Full authority to prescribe • 90-day supply limit for a single prescription • C-IV: Prescription valid for 6-months from date issued • C-V: Prescription valid for 12-months from date issued.	• Full authority to prescribe • 90-day supply limit for a single prescription • C-IV: Prescription valid for 6-months from date issued • C-V: Prescription valid for 12-months from date issued.

	Missouri Advanced Practice Registered Nurse	Missouri Assistant Physicians	Missouri Physician Assistants
Buprenorphine	• Up to a 30-day supply for patients receiving medication assisted treatment for a substance use disorder. • Must meet federal requirements (an X" DEA number is no longer issued/required) • No refills allowed***	• Up to a 30-day supply for patients receiving medication assisted treatment for a substance use disorder. • Must meet federal requirements (an X" DEA number is no longer issued/required) • No refills allowed***	• Up to a 30-day supply for patients receiving medication assisted treatment for a substance use disorder. • Must meet federal requirements (an X" DEA number is no longer issued/required) • No refills allowed***
Family Members (Controlled Substances)	No authority; Cannot prescribe controlled substances for family members as defined below [§195.070]	No authority; Cannot prescribe controlled substances for family members as defined below. [§ 334.037.12; § 334.747]	No authority; Cannot prescribe controlled substances for family members as defined below. [§ 334.037.12; § 334.747]
Self-Prescribing (Controlled Substances)	No authority; Cannot prescribe controlled substances for themselves	No authority; Cannot prescribe controlled substances for themselves [§ 334.037.12; § 334.747]	No authority; Cannot prescribe controlled substances for themselves [§ 334.037.12; § 334.747]

*** *According to BNDD, a new prescription can be written for an additional 5-day supply (30-days for buprenorphine), however, a new prescription and prescription number would have to be generated. BNDD would consider these new prescriptions and not refills.*

"Family" is defined by the state's medical board as a spouse, parent, grandparent, great-grandparent, child, grandchild, great-grandchild, brother, sister, aunt, uncle, nephew, niece, mother-in-law, father-in-law, brother-in-law, sister-in-law, daughter-in-law or son-in-law (adopted and step members are included). [20 CSR 2150-5.100(3)(G)(10)].

See F.8 for initial opioid prescription limits for the treatment of acute pain.

MID-LEVEL PRACTITIONER CONTROLLED SUBSTANCE STATUTES/RULES

- APRN: § 195.070; § 334.104.2(2); 20 CSR 2150-5.100
- Assistant Physicians: [§ 334.037; 20 CSR 2150-2.240]
- Physician Assistants: [§ 334.735; § 334.747; 20 CSR 2150-7.135]

G.4 NON-RESIDENT MID-LEVEL PRACTITIONERS

Prescriptions from non-resident mid-level practitioners may be filled in Missouri if the prescription is valid in the prescriber's home state. The following refills/quantity limits apply unless otherwise restricted by the prescriber'shome state (*controlled substance guidance provided by BNDD*):

Out-of-State Midlevel Practitioner	
Non-Controlled Prescriptions	· As authorized by the prescriber's home state
Schedule II	· Rx valid for 6-months from date issued · No refills Supply limit: · MO patient: 30-Day supply/ 90-Day supply with documented medical reason · Non-MO patient: As allowed in home state
Schedule III (Opiates & Non-Opiates)	· Rx valid for 6-months from date issued · Refills as allowed in home state. Supply limit: · MO patient: 90-Day supply · Non-MO patient: As allowed by home state.
Schedule IV & V	· C-IV prescription valid for 6-months from date issued · C-V prescription valid for 12-months from date issued · Refills as allowed in home state. Supply limit: · MO patient: 90-Day supply. · Non-MO patient: As allowed in home state.
Family Members	· As allowed by home state
Self-Prescribing	· As allowed by home state

Prescriptions from a non-resident mid-level practitioner may be filled even if similar prescriptive authority is not recognized in Missouri for the same mid-level practitioner (e.g., a non-resident

The DEA publishes a state listing of mid-level practitioners authorized to prescribe controlled substances online at https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf. *Note: This resource is not maintained by the Board and the Board cannot guarantee its accuracy.*

H.1 LABELING

A written/printed label must be affixed to each prescription container dispensed to a consumer that indicates:

1. The date the prescription was filled;
2. A prescription number or other unique identifier;
3. The patient's name;
4. The prescriber's directions for use;
5. The prescriber's name;
6. The pharmacy's name and address; *(For Class-J pharmacies, either the name and address of the pharmacy responsible for offering patient counseling or the pharmacy responsible for dispensing to the patient may be listed on the label, as designated by the pharmacies by contract)*;
7. The exact name and dosage of the drug dispensed, and;
8. If a generic substitution is made, the drug manufacturer must be identified either on the label or in the pharmacy's records by name or abbreviation. [§ 338.059].

Printing only a brand name on a dispensing label when a generic product is dispensed is misleading to the public and considered misbranding. Board inspectors have observed instances where the generic product is listed on the label with the statement "substituted for" followed by the brand name of the product. This is acceptable if the label is not misleading. However, Missouri law doesn't require that a brand name be on a label when a substitution is made.

Effective August 28, 2023, only the name of the prescribing APRN, physician assistant, or assistant physician must be listed on the container label. The collaborating physician's name is no longer required on the container label for APRN and PA controlled substance prescriptions as of August 28, 2023 [See revised § 195.100] *(The collaborating physician's name was never required for AP prescription containers).*

Missouri law does not prohibit the addition of other label information. However, prescription labels should be clear and easily readable. *Note: These labeling requirements do not apply to internal drug "orders" for in-patients of a licensed hospital.*

- *The most common label discrepancy that inspectors observe involves "PRN" in the label directions. Either "as needed" is omitted from the label directions when prescribed as "PRN," or "as needed" is included in the label directions when not prescribed as "PRN". The inclusion or exclusion of "PRN" can be clinically significant, and may result in the patient either taking more medication than needed or not taking medication when medically appropriate. This is especially important with opiates in light of the ongoing opioid crisis. Pharmacists should pay careful attention when verifying prescriptions to make sure the prescribed directions are correct.*

I.1 REPORTING OF COMPOUNDING DATA

The Federal Drug and Cosmetic Act (FDCA) provides drug products dispensed or distributed in the U.S. must comply with federal requirements related to:

1. Current good manufacturing products (cGMP),
2. Labeling with adequate directions for use, and
3. FDA approval before marketing. [See FDCA section [503(A)]

The FDCA exempts pharmacists and physicians from cGMPs, designated labeling requirements and FDA approval, if:

1. The pharmacy is in a state that has entered a compounding Memorandum of Understanding (MOU) with the FDA, or;
2. If the pharmacy's home state has not signed the MOU, the number of compounded products shipped interstate by the pharmacy/physician does not exceed 5% of the total prescription orders dispensed or distributed by the pharmacy or physician. [See FDCA section [503(A)]

In October 2020, the FDA adopted a federal/state Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products. The Board approved signing the FDA MOU in April 2020, and subsequently promulgated rule 20 CSR 2220-2.425 (Required Pharmacy Reporting), which addresses reporting of needed compounding data to comply with MOU requirements.

A third-party federal lawsuit was filed in 2021 challenging designated MOU provisions. The FDA subsequently announced in February 2022 that it intends to undertake the federal rulemaking process and stayed enforcement of the MOU pending final rulemaking.

In light of the FDA's stayed enforcement, the Board will be exercising its enforcement discretion and will extend enforcement of 20 CSR 2220-2.425 until January 31, 2025. Pharmacies do not have to file their initial compounding data reports required under 20 CSR 2220-2.425 until January 31, 2025. The 2025 report will cover 2024 compounding data. The Board recommends that pharmacies begin collecting/tracking required compounding data now to meet the 2025 deadline. *Note: Licensees should monitor the Board's website for updates on the Board's enforcement date.*

Required Reporters: Except as listed below, 20 CSR 2220-2.425 is applicable to all pharmacies located in Missouri that are compounding human drug preparations, even if the pharmacy is not compounding from bulk ingredients, does not have a Missouri Class D (Non-Sterile Compounding) or Class H (Sterile Compounding) pharmacy permit, or does not dispense/distribute compounded preparations outside of Missouri.

- 20 CSR 2220-2.425 only applies to pharmacies located in Missouri and does not apply to non- resident pharmacies *(other home state laws may apply)*.
- *Hospital Applicability:* 20 CSR 2220-2.425 applies to entities under the Board's jurisdiction. The Board does not have jurisdiction over medication compounded by a Missouri licensed hospital under the Missouri Dept. of Health and Senior Services' jurisdiction, for administration to the patient within the "licensed premises" of the hospital. However, pharmacy compounding under the Board's jurisdiction would need to be reported to the Board.

Reporting Requirements: Pharmacies have to report the following compounding data to the Board annually:

A. The number of prescriptions or medication orders for compounded human drug preparations/products that the pharmacy distributed or dispensed interstate during the previous calendar year;
B. The number of prescriptions or medication orders for compounded human drug preparations/products that the pharmacy dispensed (or caused to be dispensed) from the facility in which the drug preparations/products were compounded during the previous calendar year (e.g., not picked up on-site by the patient or the patient's designee);
C. The number of prescription or medication orders for compounded human drug preparations/products dispensed on-site at the pharmacy during the previous calendar year (e.g., picked up by the patient or the patient's designee);
D. The sum of the figures from (B) and (C) above; and
E. The quotient from dividing the figure in (A) by the figure from (D).

If the figure from section (E) above is greater than five tenths (0.5), the pharmacy must also report:

A. The total number of prescription or medication orders for sterile compounded human drugs distributed or dispensed interstate during the previous calendar year;
B. A list of the states where the pharmacy was licensed during the previous calendar year; and
C. A list of the states into which the pharmacy distributed compounded human drug preparations/products during the previous calendar year.

According to FDA Guidance, the MOU does not apply to:

- Drugs intended for veterinary use
- Repackaged drug products *(The Board's rules would require reporting of repackaged compounded sterile preparation data)*
- Radiopharmaceuticals
- Biological products subject to licensure under section 351 of the Public Health Service Act, or
- Drugs compounded by outsourcing facilities under section 503B of the FD&C Act.

Pharmacies do not have to report compounding data to the Board for the products/preparations listed above. [See also 20 CSR 2220-2.425(4) and/or FDCA Section 503(A)]

Additionally, the Board does not consider flavoring a prescription to be compounding. The Board also does not consider reconstituting or mixing ingredients for an FDA approved non-sterile drug product to be compounding (e.g., Benzaclin®, Benzamycin®, Epaned® etc.). However, the use of compounding kits that include the compounding ingredients is compounding and would fall under 20 CSR 2220-2.425's reporting requirements (e.g., First® Kits).

Compounding data reports can be manually or electronically submitted to the Board office; A sample reporting form will be available on the Board's website prior to January 2024.

Alternatively, pharmacies may electronically report compounding data to the Board via the National Association of Boards of Pharmacy's (NABP) Information Sharing Network. NABP's Information Sharing Network is currently a free electronic data exchange operated by NABP for collecting required pharmacy MOU data. Visit NABP's website for NABP registration and

technology requirements. Pharmacies may begin voluntarily reporting to NABP's Information Sharing Network now and do not have to wait until 2024.

- 20 CSR 2220-2.425's reporting requirements and calculations were taken from the FDA's final Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products. To ensure consistency, the Board did not make any substantive changes to the MOU requirements.

M.1 GENERAL AUTHORITY

Missouri's pharmacist immunization authority under § 338.010.1(4) was substantially revised by the Missouri General Assembly in 2023. Effective August 28, 2023, a Missouri licensed pharmacist may now order and administer all FDA approved or authorized vaccines to individuals at least seven (7) years old, or the age recommended by the Centers for Disease Control and Prevention, whichever is older, with the exception of the following vaccines :

- Anthrax
- Cholera
- Dengue
- Hib
- Japanese encephalitis
- Monkeypox
- Polio
- Rabies
- Rotavirus
- Smallpox
- Tick-borne encephalitis
- Tuberculosis
- Typhoid
- Yellow fever,
- Any vaccine approved after January 1, 2023

Effective August 28, 2023, pharmacists may independently order and administer vaccines under § 338.010.1(4). A protocol with a Missouri licensed physician is allowed but is no longer required to immunize under § 338.010.1(see Emergency Rule Amendment).

As required by statute, the Missouri Board of Pharmacy and the Missouri Board of Healing Arts promulgated an emergency rule amendment of rule 20 CSR 2220-6.050 to implement revised § 338.010.1(4) (see Emergency Amendment on the Missouri Secretary of State's website at: https://www.sos.mo.gov/adrules/EmergenciesforInternet/emergency)

Significantly, revised § 338.010.1(4), prohibits pharmacist administration of any vaccine approved after January 1, 2023. Emergency rule 20 CSR 2220-6.050(1) provides pharmacists may still administer a FDA approved vaccine that is reformulated or updated after January 1, 2023, if the initial vaccine was approved by the FDA prior to January 1, 2023. Pharmacists may continue to administer vaccines that are periodically/annually reformulated or updated, such as seasonal influenza vaccines, if the FDA approved the original vaccine before January 1, 2023.

Attachment A includes a list of FDA vaccines a pharmacist may administer under § 338.010.1(4), as of August 28, 2023. *(Attachment A is provided for informational purposes; Authorized vaccines may have changed since this document was published. Licensees should review the current FDA approved vaccine list to ensure compliance).*

Licensees immunizing pursuant to § 338.010.1(4) must comply with:

- All state and federal laws governing vaccine information statements and informed consent;
- Manufacturer guidelines, and;
- All applicable Centers for Disease Control (CDC) guidelines. In the event of a conflict between manufacturer guidelines and CDC guidelines, CDC guidelines control.

- The restriction on administering vaccines approved by the FDA after January 1, 2023, in § 338.010.1(4) does not apply to vaccines administered by medical prescription order under § 338.010.1(3). Pharmacists may continue to administer vaccines approved by the FDA after January 1, 2023, by medical prescription order *(See 20 CSR 2220-6.040 for additional administration by medical prescription order training requirements; A separate Notification of Intent is also required)*
- Pharmacists may not administer the recently approved Respiratory Syncytial Virus (RSV) vaccine under § 338.010.1(4), given the vaccine received initial FDA approval *after* January 1, 2023. The RSV vaccine may still be administered by medical prescription order under § 338.010.1(3) and 20 CSR 2220-6.040 (see above).

M.2 IMMUNIZATION QUALIFICATIONS [§ 338.010 and 20 CSR 2220-6.050]

Immunizing pharmacists must be competent to perform the services provided and maintain ongoing/continued competency. Immunizing pharmacists, intern pharmacists, and qualified pharmacy technicians must also meet the following qualifications in 20 CSR 2220-6.050:

IMMUNIZATION REQUIREMENTS	
Pharmacist Qualifications	• Active Missouri RPh license • Notification of Intent filed with Board (must be filed online prior to immunizing) • Current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. The CPR/BLS program must include an in-person skill assessment. • Completion of a certificate program in administering vaccines accredited by ACPE or an entity approved by the Board or provided by a regionally accredited pharmacy or medical school/college. The certificate program must include training in: 1. *Current CDC vaccine recommendations/guidelines for vaccines authorized by Chapter 338, including, immunization schedules* 2. *Basic immunology and vaccine protection* 3. *Pre- and post- vaccine screening or assessment* 4. *Physiology and techniques for administering vaccines, including, hands-on training in intramuscular, intradermal, subcutaneous and nasal administration routes and other common routes of vaccine administration, and* 5. *Identifying and treating adverse reactions, including anaphylactic reactions and needle sticks.* *** Prior to administering vaccines by a route of administration not included in the original certificate program, the pharmacist must first be trained in the route of administration by a licensed health care practitioner who is authorized to administer medication. Documentation of training/training date(s) must be kept and made available to the board on request [See Emergency Rule 20 CSR 2220-6.050(3)(D)]

Pharmacist Notification Renewal	NOIs must be refiled when your Missouri pharmacist license is renewed (every even-numbered year- 2024, 2026, etc.) To renew, pharmacists must have: • A current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. • Two (2) CE hours (0.2 CEU) related to administering vaccines or CDC immunization guidelines. CE must be completed during the biennial renewal period (Nov. 1st to Oct. 31st of even numbered years) ****Proof of CPR/BLS certification from prior years should be maintained in the event of an audit (e.g., prior certification cards/ certificates)****
Missouri Licensed Intern Pharmacists	May immunize if the intern: 1) Has a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment. 2) Has completed a certificate program in administering vaccines that meets the same requirements as the required pharmacist certificate program, & 3) Is working under the direct supervision of a pharmacist qualified to immunize
Qualified Pharmacy Technician	Pharmacists may delegate immunizations to a qualified pharmacy technician who is under the direct supervision of a qualified Missouri-licensed pharmacist if the pharmacy technician: 1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies (NCCA), and** 2. Has assisted in the practice of pharmacy as a registered or licensed pharmacy technician in Missouri or another U.S. state or territory for one (1) year, and 3. Has a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment, and 4. Has completed a certificate program in administering vaccines that meets the same requirements as the required pharmacist certificate program, and 5. Has an initial and, if applicable, annual documented competency assessment in medication administration. [20 CSR 2220-6.050(1) (D), (E)]. *A sample competency assessment checklist is available on the Board's website at: https://pr.mo.gov/boards/pharmacy/Immunizationcompetencychecklist.pdf* A Missouri licensed pharmacist must be physically present on-site and supervising when a qualified pharmacy technician is immunizing (see M.5) *** As of August 2023, the Pharmacy Tech. Certification Board (PTCB) and the National Healthcareer Assoc. (ExCPT) are NCCA accredited.*

Section 338.010.1(16) requires that pharmacists post a certificate showing that he/she has met all immunization training requirements. The Board does not issue a separate immunization certificate/license. Instead, licensees should print and display their online license verification from the Board's website which will show if a Notification of Intent has been filed. Online license verifications can be retrieved by searching the licensee's name at https://pr.mo.gov/pharmacy-licensee-search.asp. Posting an immunization training certificate does not meet the statutory requirement.

M.3 PATIENT ASSESSMENT/RECORDS

Pharmacist immunization activities must be safely and properly performed in accordance with the applicable standard of care. The pharmacist must use a screening procedure based on generally accepted clinical guidelines to identify appropriate patients for immunization. Additionally, an adequate patient or medical history must be collected as deemed necessary or appropriate to allow the pharmacist to properly assess the patient. [See Emergency Rule 20 CSR 2220-6.050(4)] Patients with a contraindication must be referred to the patient's primary care provider or an appropriate healthcare provider, as deemed necessary or appropriate by a pharmacist. [Emergency Rule 20 CSR 2220-6.050(4)]. Referrals should be documented in the patient's medical records to show proof of compliance.

Intern pharmacists and qualified pharmacy technicians authorized to administer vaccines may assist a pharmacist with screening patients or collecting patient/medical histories (e.g., form patient screening checklist/questionnaire), however, patient/medical history collection criteria/guidelines, the scope of the required patient assessment, and clinical determination of patient vaccine eligibility must be reviewed and approved by a pharmacist prior to administration.

For vaccines ordered by a pharmacist, the pharmacist must maintain a patient record of each vaccine ordered that includes:

1. The patient's name, address, and date of birth;
2. The name and dosage of any vaccine ordered;
3. The name and address of the patient's primary health care provider, as provided by the patient;
4. The identity of the ordering pharmacist;
5. Documentation of any patient screening; and
6. Any other pertinent medical or medication information/history.

> *A good faith attempt should be made to collect PCP information (e.g., verbally or on the immunization authorization form). The Board recommends documenting if the patient doesn't provide PCP information.*

After immunizing, patients must be asked to remain in the pharmacy a "safe amount of time" to observe any adverse reactions. [§ 338.010.15(2)] The Board recommends identifying the required waiting period in the pharmacy's policies/procedures or, if applicable, in the governing protocol. In the absence of protocol language, pharmacists should use their professional discretion to determine the time needed to adequately assess adverse reactions. The Board recommends documenting when a patient refuses to stay.

M.4 PHYSICIAN PROTOCOLS

Effective August 28, 2023, pharmacists may independently order and administer vaccines authorized by § 338.010.1(4), or may order/administer vaccines authorized by § 338.010.1(4) pursuant to a protocol with a Missouri-licensed physician who is actively engaged in the practice of medicine. [20 CSR 2220-6.050(5)]. A physician immunization protocol is optional and is no longer required after August 28, 2023.

Pharmacists opting to utilize a physician immunization protocol must comply with all requirements in their governing protocol, in addition to 20 CSR 2220-6.050 protocol requirements.

Protocols should clearly delineate the pharmacist's immunization authority. At a minimum, protocols must include:

1. The identity and signature of the participating pharmacist and physician;
2. The time period of the protocol;
3. Authorized vaccines;
4. The patient or groups of patients who may be vaccinated;
5. Allowed routes and anatomic sites of administration;
6. Provisions for creating a prescription for each administration under the authorizing physician's name;
7. Patient assessment or referral requirements, if applicable;
8. Emergency response procedures, including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
9. The length of time the pharmacist is required to observe a patient for adverse events;
10. Disposal procedures for used and contaminated supplies;
11. Authorization to administer vaccines at a non-pharmacy location;
12. Record keeping and any notification requirements; and
13. Provisions for terminating the protocol at the request of any party at any time.

No mileage restrictions apply to where a protocol physician may be located, however, the protocol physician must be actively engaged in the practice of medicine.

Immunization protocols may be valid for no longer than one (1) year; A new protocol must be signed each year. Protocols must be maintained for at least eight (8) years after the protocol is terminated.

Protocol Amendments: Except as provided below, amendments to an immunization protocol must be manually or electronically signed and dated by all participating pharmacists and physicians. Signatures may be included on the original protocol or on a separate document that is attached to the protocol. Protocol amendments must be signed and dated before they go into effect, and not retrospectively.

1. Additional Pharmacists: Pharmacists may be added to an existing protocol if the protocol is signed by both the newly added pharmacist and the authorizing physician(s). Existing pharmacists do not have to re-sign the protocol when a new pharmacist is added unless other protocol provisions are changed.

2. Changing/Adding Locations: Pharmacists may immunize by protocol at any Missouri-licensed pharmacy, unless otherwise restricted by the governing protocol. Authorization to immunize at a non-pharmacy location may be added to or removed from an existing protocol, if the physician signs and dates the protocol approving the change (a separate amendment document signed by the physician is acceptable). Existing pharmacists do not have to re-sign the protocol when non-pharmacy immunization authority is added/removed unless other protocol provisions are changed.

M.5 AUTHORIZED DELEGATION

Immunizations authorized by § 338.010.1(4) may be delegated to an intern pharmacist or qualified pharmacy technician who meets the training/eligibility requirements in 20 CSR 2220-6.050(1)(D). Intern pharmacists and qualified pharmacy technicians must be competent to provide delegated immunization activities, and pharmacists should assess and ensure ongoing competency. Qualified

pharmacy technicians must be supervised by a Missouri-licensed pharmacist who is also authorized to immunize under § 338.010.1(4)/20 CSR 2220-6.050 and who is physically present on-site when vaccines are administered. [[20 CSR 2220-6.050(9)]]

Intern pharmacists and pharmacy technicians do not have to file a Notification of Intent with the Board, however, the supervising pharmacist and intern pharmacist/qualified pharmacy technician must maintain proof that the intern/qualified pharmacy technician has met the required training, for a minimum of two (2) years. [20 CSR 2220-6.050(1)(D)] (See M.2 chart for intern pharmacist/qualified pharmacy technician training requirements)

- Protocol requirements may be stricter than statute/rule, in which case the governing protocol will control.
- Pharmacists should review their current immunization protocols and consult with their protocol physician to add any new vaccine authority authorized by § 338.010.1(4) after August 28, 2023.

DELEGATION TO OTHER HEALTHCARE PROVIDERS:

The Board has been asked if pharmacists can delegate their administration authority under 20 CSR 2220-6.050 to other non-pharmacy healthcare providers (e.g., a nurse, physician assistant, assistant physician). Pharmacies may use non-pharmacy healthcare providers to administer vaccines subject to the following:

1. The healthcare provider must have their own authority or their own protocol/standing order with a physician, in compliance with their regulatory agency's requirements, that gives them the authority to administer the vaccine.
2. The healthcare provider must administer the vaccine in compliance with their authority or protocol/standing order, including, any patient screening requirements.
3. The pharmacy may use their pharmacy software system to conduct billing/vaccine reporting for administrations provided by a healthcare provider. If a prescription number is assigned to the billing/reporting record, the computer record and any hard copy or image should clearly indicate that it is a billing record and not a prescription record.
4. The pharmacy must be able to account for pharmacy vaccine inventory administered by the healthcare provider via billing or distribution records.
5. For healthcare provider-administered vaccines, any hard copy vaccine administration record should be physically separated from pharmacy administration records.
6. The administering healthcare provider does not have to be registered as a pharmacy technician, unless they will have independent access to drug inventory (e.g., without a pharmacist present and supervising).

Disclaimer: This procedure has not been reviewed for insurance billing and liability concerns. For legal advice, please consult an attorney. Healthcare providers should also contact their licensing Boards for their requirements.

M.6 IMMUNIZATION LOCATIONS

Pharmacists independently ordering and administering vaccines under § 338.010.1(4) may immunize at any location (pharmacy or non-pharmacy); No restrictions apply.

Vaccines by Protocol: Unless otherwise restricted in their governing protocol, pharmacists may immunize at any Missouri licensed pharmacy. Pharmacists may immunize at a non-pharmacy location if authorized by their governing protocol. Protocols only have to identify if pharmacists are allowed to immunize at a non-pharmacy location; Specific street addresses of authorized non-pharmacy locations do not have to be listed in the protocol.

Qualified Technicians/Intern Pharmacists: Intern pharmacists and qualified pharmacy technicians may administer at any location allowed for a pharmacist, unless otherwise restricted by the supervising pharmacist or, if applicable, the physician protocol. A Missouri licensed pharmacist who is authorized to immunize must be physically present on-site and supervising when a qualified pharmacy technician is immunizing. [20 CSR 2220-6.050(9)]

M.7 PRESCRIPTION REQUIREMENTS

For vaccines ordered by a pharmacist, a prescription must be created in the ordering pharmacist's name within seventy-two (72) hours after the vaccine is dispensed.

For vaccines administered by physician protocol, the pharmacist must either obtain a prescription from the authorizing physician or create a prescription under the protocol physician's name documenting the dispensing within seventy-two hours (72) hours after administration. [20 CSR 2220-6.050(5)(D)]. The protocol physician must be listed as the prescriber and not the pharmacist for vaccines administered by protocol.

M.8 NOTIFICATIONS

Licensees must comply with the following notification requirements [20 CSR 2220-6.050(8)]:

	TIMEFRAME	NOTIFICATION REQUIREMENTS	NOTIFICATION METHOD
Adverse Events	*Within twenty-four (24) hours after learning of a patient adverse event/ reaction*	*The authorizing physician and the patient's primary care provider must be notified, if different.*	*In the pharmacist's discretion unless otherwise defined in any applicable protocol.*
Authorizing Protocol Physician (if applicable)	*As required by protocol.*	*As required by protocol* ***Physicians may choose not to be notified.***	*As required by protocol.* ***Physicians may choose not to be notified.***
Primary Care Provider	*See M.10* *(ShowMeVax Reporting)*	*See M.10* *(ShowMeVax Reporting)*	*See M.10* *(ShowMeVax Reporting)*
Vaccine Adverse Event Reporting System (VAERS)	*Within thirty (30) days after learning of a patient adverse event/reaction*	*As provided by the U.S. Department of Health and Human Services*	*Online via the VAERS system*
ShowMeVax	*See Section M.10*	*See Section M.10*	*See Section M.10*

Required notifications can be made manually or electronically, unless otherwise required by state/federal law or, if applicable, a governing protocol. Alternatively, notifications can be made through a common electronic medication record that is accessible to and shared by both the physician and pharmacist (e.g., a shared EMR/EHR). [20 CSR 2220-6.050(7)] Proof of the required notifications must be maintained in the pharmacist's records.

PCP notification is only required if the PCP's information is known. A good faith attempt should be made to collect PCP information (e.g., verbally or on the immunization authorization form). The Board suggests documenting if the patient doesn't provide PCP information.

M.9 RECORDS

Immunizing pharmacists must document and maintain a record of:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist and, if applicable, the identity of the administering intern pharmacist or qualified pharmacy technician;
6. Documentation of patient screening, if applicable;
7. Any adverse reaction and who was notified, if applicable; and
8. Any other pertinent medical or medication information/history.

Vaccination records must be maintained for at least two (2) years. If vaccines are administered on behalf of a pharmacy, records must be maintained at the pharmacy. If the vaccine is not administered on behalf of a pharmacy, records should be maintained at an address identified in advance by the pharmacist or, if applicable, in the pharmacist's immunization protocol.

For additional immunization compliance information, see the Board's Immunization Checklist online at http://pr.mo. gov/boards/pharmacy/13863[1].pdf .

M.10 SHOWMEVAX REPORTING [§ 338.010.17]

Pharmacists are required to report all vaccines administered to ShowMeVax unless the patient opts out of reporting. [§ 338.010.17] ShowMeVax is Missouri's statewide immunization registry operated by the Missouri Department of Health and Senior Services (DHSS). The registry offers health care professionals, schools and child care organizations a single location for recording immunization history and status and allows providers to monitor vaccine inventory and upcoming required doses for patients. ShowMeVax reporting is required for vaccines administered by medical prescription order and vaccines administered by protocol.

Patients must be informed on a manual or electronic form that their information will be entered into the ShowMeVax system and provided an opportunity to opt-in to reporting. The patient must manually or electronically sign the form acknowledging that their information will be reported to ShowMeVax. A sample ShowMeVax Patient Notification Form is available on the Board's website. However, licensees should consult with legal counsel to develop the appropriate notification form for your practice setting. Notification forms should be maintained in the licensee's records as proof of compliance.

If the patient opts-out of ShowMeVax reporting, pharmacists must provide the following information to the PCP in writing within fourteen (14) days after immunizing:

1) The patient's name
2) The vaccine(s) administered
3) The administration route
4) The anatomic site of administration, and
5) The administration date.

Written notifications may be transmitted electronically or by fax/e-mail. Pharmacists must maintain documentation that the required notification was provided. PCP notification is not required if the patient doesn't provide PCP information.

Section 338.010.17 does not identify when vaccines have to be reported to ShowMeVax. Pending additional rulemaking, licensees should report to ShowMeVax within fourteen (14) days after immunizing.

Licensees are required to register with DHSS to report to ShowMeVax. Registration information is available on DHSS' website at https://health.mo.gov/showmevax/smv- providers.php. Registration is free.

Questions regarding ShowMeVax online reporting/registration should be directed to DHSS' Bureau of Immunizations at (877) 813-0933 or showmevaxsupport@health.mo.gov. The Board cannot answer ShowMeVax registration questions.

PCP notification is only required if the PCP's information is known. A good faith attempt should be made to collect PCP information (e.g., verbally or on the immunization authorization form). The Board suggests documenting if the patient doesn't provide PCP information

M.11 EMERGENCY AUTHORIZATION

Effective August 28, 2023, a pharmacist may order and administer vaccines approved or authorized by the FDA to address a public health need during a state or federally declared public health emergency, as lawfully authorized by the state or federal government or an authorized state or federal agency. [See § 338.010.18] Pharmacists immunizing under § 338.010.18 must comply with applicable state/federal requirements.

N.6 PRESCRIPTION ORDERS

To provide MT [medication therapy] services, a pharmacist must obtain a prescription order from their protocol physician authorizing the pharmacist to perform MT services for a specific patient. Prescription orders for MT services are valid for no more than one (1) year and may be transmitted verbally, electronically, or in writing.

Pursuant to 20 CSR 2220-6.080(2)(A), the prescription order must include:

- The patient's name, address and date of birth;
- The date the prescription order was issued;
- The clinical indication for MT services (e.g., the patient's diagnosis or disease);
- The authorizing physician's name and address; and
- The length of time for providing MT services, if less than one (1) year.

Prescription orders maintained in compliance with 20 CSR 2220-6.080(2) will be deemed to comply with the general prescription requirements of 20 CSR 2220-2.018.

- Effective August 28, 2023, § 338.010 has been amended to remove the reference to a patient-specific prescription for medication therapy services. The Board of Pharmacy will be working with the Missouri Board of Healing Arts to promulgate joint rules to implement the new provisions, as required by § 338.010.10. Until such time, current rule 20 CSR 2220-6.080 still requires a patient-specific prescription for MT services for each patient.

ATTACHMENT A

The list is current as of August 17, 2023. ~~Stricken~~ vaccines may not be administered under revised section 338.010.1(4). See the full FDA vaccines for current vaccines: https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states

Vaccines Licensed for Use in the United States

Product Name	Trade Name
Adenovirus Type 4 and Type 7 Vaccine, Live, Oral (/vaccines-blood-biologics/vaccines/adenovirus-type-4-and-type-7-vaccine-live-oral)	No Trade Name
~~Anthrax Vaccine Adsorbed, Adjuvanted (/vaccines-blood-biologics/vaccines/cyfendus)~~	~~CYFENDUS~~
~~Anthrax Vaccine Adsorbed (/vaccines-blood-biologics/vaccines/biothrax)~~	~~Biothrax~~
~~BCG Live (/vaccines-blood-biologics/vaccines/bcg-vaccine)~~	~~BCG Vaccine~~
~~BCG Live (/vaccines-blood-biologics/vaccines/tice-bcg)~~	~~TICE BCG~~
~~Cholera Vaccine Live Oral (/vaccines-blood-biologics/vaccines/vaxchora)~~	~~Vaxchora~~
COVID-19 Vaccine, mRNA (/vaccines-blood-biologics/comirnaty)	Comirnaty
COVID-19 Vaccine, mRNA (/vaccines-blood-biologics/spikevax)	SPIKEVAX
~~Dengue Tetravalent Vaccine, Live (/vaccines-blood-biologics/dengvaxia)~~	~~DENGVAXIA~~
Diphtheria & Tetanus Toxoids Adsorbed (/vaccines-blood-biologics/vaccines/diphtheria-and-tetanus-toxoids-adsorbed)	No Trade Name
Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed (/vaccines-blood-biologics/vaccines/infanrix)	Infanrix
Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed (/vaccines-blood-biologics/vaccines/daptacel)	DAPTACEL
~~Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed, Hepatitis B (recombinant) and Inactivated Poliovirus Vaccine Combined (/vaccines-blood-biologics/vaccines/pediarix)~~	~~Pediarix~~
~~Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine (/vaccines-blood-biologics/vaccines/kinrix)~~	~~KINRIX~~
~~Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine (/vaccines-blood-biologics/vaccines/quadracel)~~	~~Quadracel~~
~~Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine (/vaccines-blood-biologics/vaxelis)~~	~~VAXELIS~~

Product Name	Trade Name
~~Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine (/vaccines-blood-biologics/vaccines/pentacel)~~	~~Pentacel~~
Ebola Zaire Vaccine, Live (/vaccines-blood-biologics/ervebo)	ERVEBO
~~Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) (/vaccines-blood-biologics/vaccines/haemophilus-b-conjugate-vaccine-meningococcal-protein-conjugate)~~	~~PedvaxHIB~~
~~Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (/vaccines-blood-biologics/vaccines/acthib)~~	~~ActHIB~~
~~Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (/vaccines-blood-biologics/vaccines/hiberix)~~	~~Hiberix~~
Hepatitis A Vaccine, Inactivated (/vaccines-blood-biologics/vaccines/havrix)	Havrix
Hepatitis A Vaccine, Inactivated (/vaccines-blood-biologics/vaccines/vaqta)	VAQTA
Hepatitis A Inactivated and Hepatitis B (Recombinant) Vaccine (/vaccines-blood-biologics/vaccines/twinrix)	Twinrix
Hepatitis B Vaccine (Recombinant) (/vaccines-blood-biologics/vaccines/recombivax-hb)	Recombivax HB
Hepatitis B Vaccine (Recombinant) (/vaccines-blood-biologics/prehevbrio)	PREHEVBRIO
Hepatitis B Vaccine (Recombinant) (/vaccines-blood-biologics/vaccines/engerix-b)	Engerix-B
Hepatitis B Vaccine (Recombinant), Adjuvanted (/vaccines-blood-biologics/vaccines/heplisav-b)	HEPLISAV-B
Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant (/vaccines-blood-biologics/vaccines/gardasil)	Gardasil
Human Papillomavirus 9-valent Vaccine, Recombinant (/vaccines-blood-biologics/vaccines/gardasil-9)	Gardasil 9
Human Papillomavirus Bivalent (Types 16, 18) Vaccine, Recombinant (/vaccines-blood-biologics/vaccines/cervarix)	Cervarix
Influenza A (H1N1) 2009 Monovalent Vaccine (/vaccines-blood-biologics/vaccines/influenza-h1n1-2009-monovalent-vaccine-csl-limited)	No Trade Name
Influenza A (H1N1) 2009 Monovalent Vaccine (/vaccines-blood-biologics/vaccines/influenza-h1n1-2009-monovalent-vaccine-medimmune-llc)	No Trade Name

Product Name	Trade Name
Influenza A (H1N1) 2009 Monovalent Vaccine (/vaccines-blood-biologics/vaccines/influenza-h1n1-2009-monovalent-vaccine-id-biomedical-corporation-quebec)	No Trade Name
Influenza A (H1N1) 2009 Monovalent Vaccine (/vaccines-blood-biologics/vaccines/influenza-h1n1-2009-monovalent-vaccine-novartis-vaccines-and-diagnostics-limited)	No Trade Name
Influenza A (H1N1) 2009 Monovalent Vaccine (/vaccines-blood-biologics/vaccines/influenza-h1n1-2009-monovalent-vaccine-sanofi-pasteur-inc)	No Trade Name
Influenza Virus Vaccine, H5N1 (/vaccines-blood-biologics/vaccines/influenza-virus-vaccine-h5n1-national-stockpile) (for National Stockpile)	No Trade Name
Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted (/vaccines-blood-biologics/vaccines/influenza-h5n1-virus-monovalent-vaccine-adjuvanted)	No Trade Name
Influenza A (H5N1) Monovalent Vaccine, Adjuvanted (/vaccines-blood-biologics/audenz)	AUDENZ
Influenza Vaccine, Adjuvanted (/vaccines-blood-biologics/fluad-quadrivalent)	Fluad Quadrivalent
Influenza Vaccine, Adjuvanted (/vaccines-blood-biologics/vaccines/fluad)	Fluad
Influenza Vaccine (/vaccines-blood-biologics/vaccines/afluria-quadrivalent-afluria-quadrivalent-southern-hemisphere)	Afluria Quadrivalent, Afluria Quadrivalent Southern Hemisphere
Influenza Vaccine (/vaccines-blood-biologics/vaccines/flucelvax-quadrivalent)	Flucelvax Quadrivalent
Influenza Vaccine (/vaccines-blood-biologics/vaccines/flulaval-quadrivalent)	Flulaval Quadrivalent
Influenza Virus Vaccine (Trivalent, Types A and B) (/vaccines-blood-biologics/vaccines/afluria-afluria-southern-hemisphere)	Afluria, Afluria Southern Hemisphere
Influenza Virus Vaccine (Trivalent, Types A and B) (/vaccines-blood-biologics/vaccines/flulaval)	FluLaval
Influenza Vaccine, Live, Intranasal (Trivalent, Types A and B) (/vaccines-blood-biologics/vaccines/flumist)	FluMist
Influenza Virus Vaccine (Trivalent, Types A and B) (/vaccines-blood-biologics/vaccines/fluarix)	Fluarix
Influenza Virus Vaccine (Trivalent, Types A and B) (/vaccines-blood-biologics/vaccines/fluvirin)	Fluvirin

Product Name	Trade Name
Influenza Virus Vaccine (Trivalent, Types A and B) (/vaccines-blood-biologics/vaccines/agriflu)	Agriflu
Influenza Virus Vaccine (Trivalent, Types A and B) (/vaccines-blood-biologics/vaccines/fluzone-fluzone-high-dose-and-fluzone-intradermal)	Fluzone, Fluzone High-Dose and Fluzone Intradermal
Influenza Virus Vaccine (Trivalent, Types A and B) (/vaccines-blood-biologics/vaccines/flucelvax)	Flucelvax
Influenza Vaccine (Trivalent) (/vaccines-blood-biologics/vaccines/flublok)	Flublok
Influenza Vaccine (Quadrivalent) (/vaccines-blood-biologics/vaccines/flublok-quadrivalent)	Flublok Quadrivalent
Influenza Vaccine,Live, Intranasal (Quadrivalent, Types A and Types B) (/vaccines-blood-biologics/vaccines/flumist-quadrivalent)	FluMist Quadrivalent
Influenza Virus Vaccine (Quadrivalent, Types A and Types B) (/vaccines-blood-biologics/vaccines/fluarix-quadrivalent)	Fluarix Quadrivalent
Influenza Virus Vaccine (Quadrivalent, Types A and Types B) (/vaccines-blood-biologics/vaccines/fluzone-quadrivalent-fluzone-high-dose-quadrivalent-fluzone-intradermal-quadrivalent-fluzone)	Fluzone Quadrivalent
~~Japanese Encephalitis Virus Vaccine, Inactivated, Adsorbed (/vaccines-blood-biologics/vaccines/ixiaro)~~	~~Ixiaro~~
Measles, Mumps and Rubella Vaccine, Live (/vaccines-blood-biologics/priorix)	PRIORIX
Measles, Mumps, and Rubella Virus Vaccine, Live (/vaccines-blood-biologics/vaccines/measles-mumps-and-rubella-virus-vaccine-live)	M-M-R II
Measles, Mumps, Rubella and Varicella Virus Vaccine Live (/vaccines-blood-biologics/vaccines/proquad)	ProQuad
Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine (/vaccines-blood-biologics/vaccines/menveo)	MENVEO
Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (/vaccines-blood-biologics/vaccines/menactra)	Menactra
Meningococcal Group B Vaccine (/vaccines-blood-biologics/vaccines/bexsero)	BEXSERO
Meningococcal Group B Vaccine (/vaccines-blood-biologics/vaccines/trumenba)	TRUMENBA

Product Name	Trade Name
Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined (/vaccines-blood-biologics/vaccines/menomune-acyw-135)	Menomune-A/C/Y/W-135
Meningococcal (Groups A, C, Y, W) Conjugate Vaccine (/vaccines-blood-biologics/menquadfi)	MenQuadfi
Plague Vaccine	No trade name
Pneumococcal Vaccine, Polyvalent (/vaccines-blood-biologics/vaccines/pneumovax-23-pneumococcal-vaccine-polyvalent)	Pneumovax 23
Pneumococcal 13-valent Conjugate Vaccine (/vaccines-blood-biologics/vaccines/prevnar-13) (Diphtheria CRM_{197} Protein)	Prevnar 13
Pneumococcal 15-valent Conjugate Vaccine (/vaccines-blood-biologics/vaccines/vaxneuvance)	VAXNEUVANCE
Pneumococcal 20-valent Conjugate Vaccine (/vaccines-blood-biologics/vaccines/prevnar-20)	Prevnar 20
~~Poliovirus Vaccine Inactivated (Human Diploid Cell)~~	~~Poliovax~~
~~Poliovirus Vaccine Inactivated (Monkey Kidney Cell) (/vaccines-blood-biologics/vaccines/ipol-poliovirus-vaccine-inactivated-monkey-kidney-cell)~~	~~IPOL~~
~~Rabies Vaccine (/vaccines-blood-biologics/vaccines/imovax)~~	~~Imovax~~
~~Rabies Vaccine (/vaccines-blood-biologics/vaccines/rabavert-rabies-vaccine)~~	~~RabAvert~~
~~Rabies Vaccine Adsorbed~~	~~No Trade Name~~
~~Rotavirus Vaccine, Live, Oral (/vaccines-blood-biologics/vaccines/rotarix)~~	~~ROTARIX~~
~~Rotavirus Vaccine, Live, Oral, Pentavalent (/vaccines-blood-biologics/vaccines/rotateq)~~	~~RotaTeq~~
~~Respiratory Syncytial Virus Vaccine (/vaccines-blood-biologics/abrysvo)~~	~~ABRYSVO~~
~~Respiratory Syncytial Virus Vaccine, Adjuvanted (/vaccines-blood-biologics/arexvy)~~	~~AREXVY~~
~~Smallpox and Monkeypox Vaccine, Live, Non-Replicating (/vaccines-blood-biologics/jynneos)~~	~~JYNNEOS~~
~~Smallpox (Vaccinia) Vaccine, Live (/vaccines-blood-biologics/vaccines/acam2000)~~	~~ACAM2000~~
Tetanus & Diphtheria Toxoids, Adsorbed (/vaccines-blood-biologics/vaccines/tdvax)	TDVAX
Tetanus & Diphtheria Toxoids Adsorbed for Adult Use (/vaccines-blood-biologics/vaccines/tenivac)	TENIVAC

Product Name	Trade Name
Tetanus Toxoid Adsorbed (/vaccines-blood-biologics/vaccines/diphtheria-and-tetanus-toxoids-adsorbed)	No Trade Name
Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (/vaccines-blood-biologics/vaccines/adacel)	Adacel
Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (/vaccines-blood-biologics/vaccines/boostrix)	Boostrix
~~Tick-Borne Encephalitis Vaccine (/vaccines-blood-biologics/ticovac)~~	~~TICOVAC~~
~~Typhoid Vaccine Live Oral Ty21a (/vaccines-blood-biologics/vaccines/vivotif)~~	~~Vivotif~~
~~Typhoid Vi Polysaccharide Vaccine (/vaccines-blood-biologics/vaccines/typhim-vi)~~	~~TYPHIM Vi~~
Varicella Virus Vaccine Live (/vaccines-blood-biologics/vaccines/varivax-refrigerated-and-frozen-formulations)	Varivax
~~Yellow Fever Vaccine (/vaccines-blood-biologics/vaccines/yf-vax)~~	~~YF-Vax~~
Zoster Vaccine, Live, (Oka/Merck) (/vaccines-blood-biologics/vaccines/zostavax)	Zostavax
Zoster Vaccine Recombinant, Adjuvanted (/vaccines-blood-biologics/vaccines/shingrix)	SHINGRIX

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